



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/617,372

07/11/2003

Mark G. Gilreath

P-4438-US

2855

49443 7590 04/29/2008
Pearl Cohen Zedek Latzer, LLP
1500 Broadway
12th Floor
New York, NY 10036

EXAMINER

KISH, JAMES M

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

04/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/617,372	Applicant(s) GILREATH ET AL.	
	Examiner JAMES KISH	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-11 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-11 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-11 and 18-24 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-10 and 18-20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. (US Patent No. 5,681,260) in view of any of Meron et al. (US Patent App. No. 2002/0042562), Takahashi'181 (US Patent No. 4,500,181), Brown (US Patent No. 6,966,906) and Takahashi'867 et al. (US Patent No. 4,942,867).

Ueda et al.

Ueda discloses a guiding apparatus for guiding an insertable body within an inspected object. As illustrated in Figure 2, the insertable tip of the device comprises an imaging unit (see column 7, line 53 through column 8, line 12) and a functional unit is provided in several of the embodiments (see column 23, lines 33-34; it states, "... can be applied not only to an endoscope but also to a catheter."). As mentioned further in Claim 4, the functional element may encompass a catheter. As illustrated in Figure 1(a), a controlling apparatus is included in the Ueda device. In one embodiment, an

LED is utilized as the illumination device powered by a battery (see column 18, lines 9-27 and Figure 27). Information and instruction can be sent wirelessly between the device and the controlling apparatus (column 18, lines 27-38). Also, sensors such as pH and temperature sensors may be provided (column 18, lines 52-60). Information can be passed to and from the device via a transmitter and a receiver (column 18, lines 18-20). Within the process circuit, there is a memory unit, as described in column 24, lines 35-47.

Ueda in view of Meron

However, Ueda does not disclose a device wherein the illumination source and the image sensor are behind a single optical window. Meron teaches an endoscopic device which includes an optical window behind which are positioned illumination sources and an imaging device (paragraph 29). Figure 4 of Meron demonstrates an embodiment in which the imaging device may be attached to the distal end of a drain catheter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a single optical window as taught by Meron in the system of Ueda to reduce materials and complexity of such a device by requiring the manufacture of one window instead of two.

Ueda in view of Takahashi'181

However, Ueda does not disclose a device wherein the illumination source and the image sensor are behind a single optical window. Takahashi'181 teaches an

endoscopic device in which a prism is placed in front of both illumination sources and an imaging unit (see Figures 4, 12 and 15-17). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a single optical window as taught by Takahashi'181 in the system of Ueda to reduce materials and complexity of such a device by requiring the manufacture of one window instead of two.

Ueda in view of Brown

However, Ueda does not disclose a device wherein the illumination source and the image sensor are behind a single optical window. Brown teaches a plastic extrusion which encloses bundles of very small diameter optical fibers for illumination and viewing tissues in vivo (column 5, lines 50-52). Through operation of the device the fibers are brought into the field of view of lens **46** at the termination of fiber bundles **39** (column 6, lines 1-3). See Figures 5c and 5d. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a single optical window as taught by Takahashi'181 in the system of Ueda to reduce materials and complexity of such a device by requiring the manufacture of one window instead of two.

Ueda in view of Takahashi'867

However, Ueda does not disclose a device wherein the illumination source and the image sensor are behind a single optical window. Takahashi'867 teaches a distal end of an endoscope which is provided at the distal end of the insert part of the endoscope, comprising an illuminating window through which illumination light is

emitted, a viewing window disposed side by side with the illuminating window to take a light image into an objective optical system, and a single transparent cover continuously covering the respective surfaces of the illuminating and viewing windows (see Abstract). Also see Figure 5. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a single optical window as taught by Takahashi'867 in the system of Ueda so that water or other external matter will not enter the endoscope (column 1, lines 15-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of any of the above references described in the rejection of claims 1-4, 7-10 and 18-20 and 22-23, and further in view of Ishikawa et al. (US Patent No. 6,264,611). The Ueda combinations are described above. However, the wireless transmission is not explicitly described as being RF energy. Ishikawa discloses a ball-shaped monitoring device for use with an instrument that is insertable into a human body. One

application of the ball sensor is to place it at the tip of a guidewire used in interventional procedures, such as balloon angioplasty (column 4, lines 45-65). Figure 3 shows a balloon catheter system that could utilize the ball sensor. The figure shows a guidewire 10 at the non-inserted end. The device may be made of silicon or metals (column 15, lines 16-30). The ball sensor provides information to a remote processing system via RF signals. See Figure 7. Column 18, lines 15-38 discuss various applications of the ball sensor, including use with ultrasound and other imaging catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize RF energy as the means to provide a wireless connection as taught by Ishikawa as a well known method to those of skill in the art.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of any of the above references described in the rejection of claims 1-4, 7-10 and 18-20 and 22-23, and further in view of Snoke et al. (US Patent No. 5,846,221). The Ueda combinations are described above. However, Ueda does not state that the device is disposable. Snoke teaches a steerable catheter having a disposable module and sterilizable handle. The module includes an imaging means to be positioned within the body of the handle for transmitting images from within the human body (column 18, lines 55-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a disposable insert portion because these small or narrow working channels or lumens are difficult to clean and sterilize (column 2, lines 15-17).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art
Unit 3737

JMK